

b.) Remarks

Claims 1 has been amended in order to recite the invention with the specificity required by statute. Claims 4, 5 and 22-37 have been cancelled as being superfluous or in order to reduce the issues. Claims 38-44 are added to more specifically recite various preferred embodiments of the present invention.

The subject matter of the amendment is found throughout the specification as filed, see page 16, lines 7-12, page 17, lines 5-10, page 18, lines 2-7, page 20, lines 9-16, page 24, lines 11-20, page 26, lines 11-15, from page 28, line 6 to page 31, line 2, and Examples 5-8, 13 and 24-25. Accordingly, no new matter has been added.

Claims 1-5 and 22-26 are rejected under 35 U.S.C. §112, second paragraph, as being:

- a) incomplete for omitting essential steps,
- b) unclear as to in which of options (i) and (ii) Applicants intend to measure hydrogen peroxide or measure reduced coenzyme,
- c) unclear how hydrogen peroxide or a reduced coenzyme are measured,
- d) unclear if the phrase “in an aqueous medium comprising” refers to one or both of options (i) and (ii),
- e) claim 22 is unclear, and
- f) insufficient antecedent basis for the limitation “the formed hydrogen peroxide”.

Points a), b), d), e) and f) are addressed above. As to c), Applicants wish to clarify that measuring hydrogen peroxide or a reduced coenzyme formed by enzymatic

reactions was well-known at the time of the present application was filed (see, for example, U.S. Patent No. 6,818,414, column 7, lines 44-52 and U.S. Patent No. 7,208,287, column 6, line 66 to column 7, line 31).

Claim 1 and claims 1-3 are rejected under 35 U.S.C. §102(b) as being anticipated by Takayuki (JP9-285298) and Hama (WO 97/40376), respectively. Claims 1-5 and 22-26 are rejected under 35 U.S.C. §103(a) as being obvious over Takayuki and Hama in view of Miki (U.S. Patent No. 6,162,607).

These rejections are respectively traversed.

As the Examiner is aware, claim 1 relates to a method of quantitatively determining HDL cholesterol using either polyoxyethylene alkylamine or polyoxyethylene alkenylamine as a non-ionic surfactant, and dextran sulfate (or a salt thereof) as a polyanion.

This particular subject matter is disclosed by neither Takayuki nor Hama. That is, Takayuki teaches using the non-ionic surfactant N-ocytl- β -glucoside and Hama teaches using the non-ionic surfactant n-heptyl- β -D-glucoside. Nor is this deficiency addressed by Miki, since as discussed below the present invention achieves results which are unexpectedly superior over both the primary references, as evidenced by the accompanying Declaration under Rule 132 of Yuki Katayama.

In the Declaration, Mr. Katayama explains (see Table 2 at page 4) that when HDL cholesterol is measured according to the present invention (Kit "A" using polyoxyethylene dodecylamine), the correlation co-efficient ca. 61.3% more accurate than the correlation co-efficient obtained using formulae representative of the closest prior art

(Kits “a-d” using polyoxyethylene octylphenyl ether, polyoxyethylene nonylphenyl ether, n-octyl-β-D-thioglucoside and n-heptyl-β-D-thioglucoside, respectively).¹

This improvement in accuracy is plainly of great utility to the skilled artisan and is entirely unsuggested by the prior art.

In view of the above amendments and remarks, Applicants submit that all of the Examiner’s concerns are now overcome and the claims are now in allowable condition. Accordingly, reconsideration and allowance of this application is earnestly solicited.

Claims 1-3 and 38-44 remain presented for continued prosecution.

Applicant’s undersigned attorney may be reached in our New York office by telephone at (212) 218-2100. All correspondence should continue to be directed to our below listed address.

Respectfully submitted,

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¹ $((0.98/((0.57 + 0.70 + 0.57 + 0.59)/4)) \times 100) - 100$